K131854

9. 510(K) SUMMARY

Submission Date: June 18, 2013

Submitter Information:

Company Name:
Or-Nim Medical Ltd.

Company Address:
Atir Yeda St.
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SEP 13 2013

Device Information:

Trade Name:	CerOx Model 3215FO
Common Name:	Flowmeter, blood, cardiovascular
Classification Name:	Cardiovascular blood flowmeter (21 CFR 870.2100)
Product Code:	DPW
Regulatory Class:	II

Predicate Device: CerOx 3210F, Or-Nim Medical Ltd.

Device Description: The CerOx Model 3215FO uses the well-established principles of near infrared spectroscopy (NIRS) and flowmetry to monitor blood flow in tissue.

CerOx Model 3215FO is identical to the CerOx Model 3210F technically and operationally.

Intended Use: The CerOx Model 3215FO is intended to monitor blood flow in tissue

Indications for Use: The non-invasive CerOx 3215FO monitor is intended for use as an adjunct monitor of microcirculation blood flow in tissue. The CerOx 3215FO monitor is intended for monitoring of adults. The prospective clinical value of data from the CerOx 3215FO monitor has not been demonstrated in disease states. The CerOx 3215FO monitor should not be used as the sole basis for diagnosis or therapy.

Comparison to Predicate Device: The CerOx 3215FO is identical to the CerOx 3210F technically and operationally, and has the same intended use and indications for use as the CerOx 3210F with respect to blood flow monitoring.

Tests performed: The optical output power of the lasers and the acoustic output power of the ultrasound transducers of the CerOx 3125FO was tested and found to be equivalent to that emitted by the CerOx 3210F. In addition the amplitude of the light signals detected by the CerOx 3215FO on a laboratory set up was tested and found to be equivalent to that detected by the CerOx 3210F.

Conclusions: The tests performed on CerOx Model 3215FO support the conclusion that it remains as safe and effective as, and remains substantially equivalent to the cleared predicate device CerOx 3210F for the monitoring of microcirculation blood flow in tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

Or-Nim Medical Ltd.
Mr. Micha Oestereich
QA/RA Director
15 Atir Yeda Street
Kfar Saba, 4464312
Israel

Re: K131854
Trade/Device Name: CerOx Model 3215FO
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular blood flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: August 7, 2013
Received: August 16, 2013

Dear Mr. Oestereich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for: Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K131854

Device Name: CerOx Model 3215FO

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Neil R Ogden
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ___K131854_____